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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,372	08/15/2003	Dusan Pavcnik	PA-5213-CIP2	2552

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COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/642,372

Applicant(s)

PAVCNIK ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 12-15, 19, 23-26, 30-35 and 37-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 11, 16-18, 20-22, 27, 28 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 8, 9, 11, 20, 27, and 36 in the reply filed on November 1st, 2006 is acknowledged.
2. Applicants' cancellation of claims 10 and 29 in the reply filed on November 1st, 2006 is acknowledged.

Priority

3. According to the RELATED APPLICATIONS section of the disclosure, the pending application (10/642,372) claims priority from provisional application 60/403,783 (filed August 15, 2002), which is a continuation-in-part of application 09/777,091 (filed February 5, 2001).
4. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are directed to subject matter (i.e., centering support element 164) introduced for the first time in provisional application 60/403,783 (filed August 15, 2002). Said subject matter was not disclosed in 60/087,661, 60/180,002, 09/324,382 or 09/777,091. Thus, the effective filing date for the subject matter of claims 8-11, 16-18, 20-22, 27-29, and 36 is August 15, 2002.
5. The Applicant traversed the above statement indicating that the subject matter of claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 (i.e., centering support element 164) has "exemplary support" in Figures 35, 37, and 40 of US Application 09/777,091 (filed February 5, 2001). However, upon reviewing those Figures, it is noted that none show/disclose a "centering support element". Further, the written disclosure of US Application 09/777,091 does not describe (or

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make reference to) a "centering support element". In addition, Figures 51-86 of the instant application (10/642,372) are not part of the disclosure of US Application 09/777,091.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1-33 of U.S. Patent No. 6,200,336, (ii) claims 1-21 of U.S. Patent No. 6,508,833, and (iii) 1-12 of U.S. Patent No. 6,974,474. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the difference between claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 of the application and (i) claims 1-33 of U.S. Patent No. 6,200,336, (ii) claims 1-21 of U.S. Patent No. 6,508,833, and (iii) 1-12 of U.S. Patent No. 6,974,474 lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of (i) claims 1-33 of U.S. Patent No. 6,200,336, (ii) claims 1-21 of U.S. Patent No. 6,508,833, and (iii) 1-12 of U.S. Patent No. 6,974,474 is in effect a "species" of the "generic" invention of claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 8-11, 16-18, 20-22, 27-29, and 36 are anticipated by (i) claims 1-33 of U.S. Patent No. 6,200,336, (ii) claims 1-21 of U.S. Patent No. 6,508,833, and (iii) 1-12 of U.S. Patent No. 6,974,474, it is not patentably distinct from (i) claims 1-33 of U.S. Patent No. 6,200,336, (ii) claims 1-21 of U.S. Patent No. 6,508,833, and (iii) 1-12 of U.S. Patent No. 6,974,474.

8. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

- (i) Claims 1-16 and 55-65 of copending Application No. 09/777,091;
- (ii) Claims 1, 7, and 14-25 of copending Application No. 10/721,582;
- (iii) Claims 1-19 and 22-42 of copending Application No. 10/910,490;
- (iv) Claims 1-20 of copending Application No. 11/185,272; and
- (v) Claims 1-29 of copending Application No. 10/828,716.

Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications claim a valve prosthesis comprising leaflets and a support frame/stent

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enclosed in (and supporting) said leaflets. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 8, 9, 11, 16, 18, 20-22, 27, 28, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bessler et al. (US 5,855,601 A).

Referring to Figures 1-7 (particularly Figures 4, 6, and 7), Bessler et al. discloses a valve prosthesis (e.g., valve prosthesis 30, 50, and 60) comprising:

- (i) A support frame (e.g., stents 32, 52, 62) supporting one or more leaflets (e.g., leaflets 36), the one or more leaflets including a co-aptation position (i.e., the one or more leaflets co-apt when their inner edges seal, close, fit together, or contact one another in order to close the valve orifice/opening), wherein the support frame and one or more leaflet form a valve that restrict blood flow in a first direction and allow blood flow in a second, opposite direction when the valve prosthesis is implanted in a vascular vessel;
- (ii) The support frame comprising frame elements/struts (e.g., straight sections 33, 53 and/or bends 34, 54) to which the one or more leaflets are attached, wherein outer edges (e.g., see bends

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and/or straight sections in cuff portion 37) of the frame elements contact/engage the wall of the vascular vessel (see Figures 1-7); and

(iii) At least one centering support element (Figure 7: wave 61 and/or barbs 64) *configured to center* (emphasis added to the functional language) the co-aptation position (see column 4, lines 12-26; column 5, line 60 to column 6, line 2). Bessler et al. disclose the valve material as comprising one of several materials, including materials capable of remodeling (e.g., pericardium).

Response to Arguments

11. Applicants' arguments filed November 1st, 2006 have been fully considered but they are not persuasive.

The Applicants argue that the stent disclosed by Bessler et al. '601 "does not support the leaflets of the valve member at any point adjacent the valve opening". The Examiner respectfully disagrees. The term "adjacent" is generally defined as "lying near, close, or contiguous"; "nearby". The support frame disclosed by Bessler et al. '601 does support (directly, or indirectly) the leaflets of the valve member at a point "lying near, close, or contiguous; nearby" the valve opening.

12. Claims 8, 9, 11, 16-18, 20-22, 27, 28, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Thorpe et al. (US 2003/0130726 A1).

Referring to Figures 9, 11, and 14-16 (particularly Figures 14-16), Thorpe et al. discloses a valve prosthesis (e.g., devices 133, 167) comprising:

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- (i) A support frame (Figures 14-16: upper stent) supporting one or more leaflets (e.g., valve material 146), the one or more leaflets including a co-aptation position (i.e., the one or more leaflets co-apt when their inner edges seal, close, fit together, or contact one another in order to close the valve orifice/opening), wherein the support frame and one or more leaflet form a valve that restrict blood flow in a first direction and allow blood flow in a second, opposite direction when the valve prosthesis is implanted in a vascular vessel;
- (ii) The support frame comprising frame elements/struts (e.g., straight sections 137, 174 AND/OR eye-loops (bends) connecting the straight sections AND/OR marginal retaining members 140, 181) to which the one or more leaflets are attached, wherein outer edges of the frame elements contact/engage the wall of the vascular vessel, at least a portion of the support frame supporting (directly, or indirectly) the leaflets of the valve member at a point adjacent (i.e., “lying near, close, or contiguous; nearby”) the valve opening (e.g., inner edge 153); and
- (iii) At least one centering support element (**first interpretation:** Figures 14-16, lower stent; **second interpretation:** Figures 14-16, any of the straight sections of the upper stent) *configured to center* (emphasis added to the functional language) the co-aptation position. Thorpe et al. disclose the valve material as comprising one of several materials, including remodelable SIS or extracellular collagen matrix (see paragraph 0037).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. (US 5,855,601 A) in view of Cox (US 5,713,950 A).

Bessler et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa (an Extracellular Collagen Matrix). However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Bessler et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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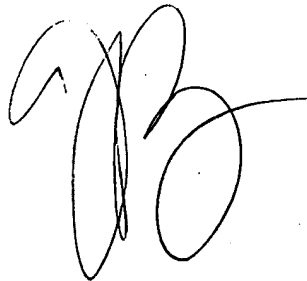

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

January 19, 2007

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.A handwritten signature in black ink, appearing to read 'D. Willse', with a long horizontal stroke extending to the right.

David H. Willse
Primary Examiner